

The premoistened wipe of the present invention requires topical delivery and not transdermal delivery. Hence, as the wipe of the present invention is not used transdermally, it cannot be used in a materially different process. As the Examiner's restriction requirement fails to meet the standard, it is improper. Applicants respectfully request the Examiner to reconsider and withdraw the restriction requirement.

**35 U.S.C. § 112 Rejection:**

The Examiner rejects Claims 8 - 9 and 15 - 16 under 35 U.S.C. § 112, second paragraph as indefinite because a property is used to define the antimicrobial protease inhibitor of the present invention.

Applicants respectfully disagree with the Examiner's rejection. A material may be defined in terms of its physical properties or its function. *In re Metcalf and Lowe*, 410 F.2d 1378 (C.C.P.A. 1969); *In re Goffe*, 526 F.2d 1393 (C.C.P.A. 1975); see also *In re Barr*, 444 F.2d 588 (C.C.P.A. 1971) cited in M.P.E.P. § 2173.05(g).

"A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used." M.P.E.P. § 2173.05(g)

"There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper." M.P.E.P. § 2173.05(g) citing *In re Swinehart*, 439 F.2d 210 (C.C.P.A. 1971).

The terms "IC<sub>50</sub>" (Claims 8 and 15 of the instant application) and "minimum inhibitory concentration" (Claims 9 and 16 of the instant application) are terms well known in the art. The term "IC<sub>50</sub>" is defined on page 14, lines 15 - 25 and page 15, lines 1 - 7. The term "minimum inhibitory concentration" is defined on page 18, lines 16 - 31. Furthermore, support for Claims 8 and 15 are found on page 14, lines 15 - 25; pages 15 - 16; page 19, lines 1 - 7; and Table I on page 20. Support for Claims 9 and 16 are found on page 18, lines 16 - 31; page 19, lines 1 - 7; page 20, lines 5 - 20 and Table II; and page 21, lines 1 - 17 and Table III.

Hence, as the Examiner's § 112, second paragraph rejection is overcome, Applicants respectfully request the Examiner to reconsider and withdraw this rejection and allow the claims in the instant application.

**35 U.S.C. § 103 Rejection:**

The Examiner rejects Claims 1 - 3, 5, 7, and 10 - 12 under 35 U.S.C. § 103(a) as being unpatentable over U.S. 5,629,081 issued to Richards et al. on May 13, 1997 in view of U.S. 5,230,897 issued to Griffin et al. on July 27, 1993. Claims 1 and 2 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. 5,871,763 issued to Luu et al. on February 16, 1999 in view of Griffin et al. '897.

Richards et al. '081 purports to teach a wet wipe and an aqueous lotion. The lotion includes a preservative to provide for long-term storage and to inhibit microbial activity in the lotion. [Richards et al. '081, 4:57-67] Richards et al. does not teach either expressly or impliedly a premoistened wipe having an antimicrobial protease inhibitor.

Griffin et al. '897 teaches a transdermal patch for delivering pentamidine into the bloodstream. Griffin et al. defines "transdermal delivery" as percutaneous delivery of a material into the bloodstream (i.e.; absorption of a material through the skin into the bloodstream). [Griffin et al. '897, 3:20-25] Griffin et al. also teaches the use of a penetration enhancer to enhance percutaneous administration of the material into the bloodstream. [Griffin et al. '897, 4:32-35] The penetration enhancer must increase the rate of delivery of the material into the bloodstream. [Griffin et al. '897]

Luu et al. '763 purports to teach a substrate treated with a lotion composition. The lotion can optionally include a medicinal agent.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success *must both* be found in the prior art, and *not* based on applicant's disclosure (emphasis added)." M.P.E.P. §2142 citing *In re Vacek*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

"To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." M.P.E.P. §2142 citing *Ex parte Clapp*, 227 U.S.P.Q. 972, 973 (Bd. Pat. App. & Inter. 1985).

"The prior art must suggest the desirability of the claimed invention." "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." M.P.E.P. 2143.01.

"A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." M.P.E.P. 2141.02 citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), *cert. denied* 469 U.S. 851 (1984).

The Examiner indicates that it would have been obvious to modify the lotioned wet wipe of Richards et al. '081 or the wet wipe of Luu et al. '763 to "use pentamidine as a protease inhibitor for the treatment of protozoal and fungal diseases as disclosed by Griffin et al. '897". Applicants respectfully disagree. Neither Richards et al., Luu et al., nor Griffin et al. discloses using pentamidine as an antimicrobial protease inhibitor.

As noted by the Examiner, Griffin et al. does disclose the use of pentamidine as an anti-protozoal and fungicidal agent [Griffin et al. '897, 1:12-15]. Griffin et al. also discloses the use of pentamidine to treat pneumonia. [Griffin et al. '897, 3:46-49] However, none of these uses suggest either expressly or impliedly that pentamidine is an antimicrobial protease inhibitor effective at controlling diaper dermatitis or any of the components suspected of causing diaper dermatitis disclosed in Applicants' application. [See instant application page 2, lines 8 - 11] Furthermore, none of these uses either expressly or impliedly suggest the topical use of pentamidine.

Griffin et al. '897, clearly teaches away from the use of pentamidine as a topical agent. The whole objective and purpose of Griffin et al. '897 is to apply pentamidine transdermally in order to deliver pentamidine into the bloodstream and away from the skin as quickly and efficiently as possible. [Griffin et al. '897, 3:6-31, 4:16-50] Conversely, the objective of the present invention is to deliver a topical benefit to the skin in order to prevent the formation of diaper dermatitis on the skin. It is desirable that the antimicrobial protease inhibitor remain on the skin. [Instant Application page 2, lines 12 - 28] A systemic delivery of pentamidine as taught by Griffin et al. would be unable to accomplish the objective of this present invention. Furthermore, the systemic delivery of pentamidine taught by Griffin et al. provides totally the opposite result of the present invention.

Griffin et al. not only does not consider the topical application of pentamidine but even suggests that the application of pentamidine to the skin might have a deleterious effect on the skin. [Griffin et al. '897, 5:36-44] This is further evidence of the unobviousness and the surprising results of the present invention.

Applying the teachings of either Richards et al. '081 in view of Griffin et al. '897 or Luu et al. '763 in view of Griffin et al. '897, one of ordinary skill would be led to believe that the application of pentamidine to the wipe of Richards et al. '081 or the wipe of Luu et al. '763 could cause a deleterious impact on the skin and hence would be led away from utilizing either of these combinations.

As Richards et al. '081 in view of Griffin et al. '897 and Luu et al. '763 in view of Griffin et al. both provide results totally opposite that of the present invention, the present invention is unobvious. Hence, as the Examiner's obviousness rejection is overcome, Applicants request the Examiner to reconsider and withdraw this rejection and allow the claims in the instant application.

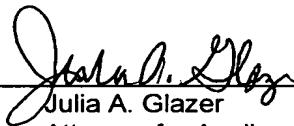
## SUMMARY

As the restriction requirement imposed by the Examiner is improper, Applicants respectfully request the Examiner to reconsider and withdraw this requirement.

As the rejections under 35 U.S.C. §§ 112 and 103(a) have been overcome, Applicants respectfully request the Examiner to reconsider and withdraw these rejections and allow the claims in the instant application.

Applicants gratefully acknowledge the Examiner's finding of allowable subject matter in Claims 4, 6, and 13 - 14.

Respectfully submitted,

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